

REMARKS

Claims 1-2, 4, 8, 16, 17, 19, 23-31 and 33 are pending.

Rejections Under 35 USC §103(a)

Claims 1-2, 4, 8, 16, 17, 19, 23-31 and 33 were rejected as being obvious in light of Belef (US Pub. 2002/0147496) in view of Pernia (US Pat. 5,634,945). Applicants respectfully traverse this rejection. This rejection is respectfully traversed because a *prima facie* case of obviousness of Applicants' claimed invention has not been established, in that all the elements of the rejected claim are not disclosed or suggested in the cited art. In re Ochiai, 37 USPQ 1127, 1131 (Fed. Cir. 1995). ("The test for obviousness *vel non* is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.'"). "To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03. However, the Belef and Pernia references alone or in combination do not teach all the claim elements, for instance, neither reference discloses tissue promoting material.

The Examiner carries the burden to establish a *prima facie* case of obviousness, In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). To establish a *prima facie* case of obviousness, there must be, a) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; b) a reasonable expectation of success and c) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §706.02(j). The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done, "[t]o support the conclusion that the claimed invention is

directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See also, MPEP §§ 2144 - § 2144.09. "Impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." MPEP § 2142.

Belef does not teach or disclose tissue promoting material. In particular, the paragraphs cited in the Office Action, ¶¶61 and 65, do not disclose any fill material that will promote tissue growth as recited in independent claims 1, 2, 8, 16 and 24. The material disclosed in the Belef reference merely acts as filler and does not promote new tissue generation. In support of this argument, a Declaration from Dr. Michael MacMillan is attached hereto and incorporated in its entirety herein.

With respect to the Pernia reference, Pernia actually teaches away from promoting tissue growth. Pernia is directed to using hair as an inert filler in the place of soft tissue, such as for example, breast implants. Pernia describes tests that were performed on rats utilizing hair as a filler material. In describing the success of the tests, Pernia explains that no tissue growth was detected, at Column 4, lines 16-17, Pernia states that, "There was no evidence of resorption or substitution by fibrotic material." (emphasis added). As with Belef, Pernia only discloses the use of material to fill or replace tissue. There is no disclosure in Pernia of promoting tissue growth. In fact, Pernia argues that tissue growth is undesirable and seeks to avoid any interaction with the surrounding tissue. (See e.g. Col. 4, ln 6-34). In contrast, the fill material disclosed by Applicants is meant to interact with the surrounding tissue to promote and stimulate new tissue growth.

Belef and Pernia, either alone or in combination do not teach or suggest all the claim limitations, for instance Belef and Pernia do not teach the use of tissue promoting material. Accordingly, it is respectfully submitted that a *prima facie* case of the obviousness of independent claims 1, 2, 8, 16 and 24 has not, and cannot, be established by the Belef and Pernia references.

With respect to specific features noted by the office action in the claims depending from claims 1, 2, 8, 16 and 24, these issues are not commented on further here because they are presently moot given the above analysis, although Applicants do not acquiesce in the Examiner's position. Furthermore, because dependent claims 4, 17, 19, 23, 25-31 and 33 further define independent claims 1, 8, 16 and 24 respectively, Applicant respectfully submits that these claims are also allowable. See MPEP § 2143.03 ("If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.")

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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